Remarks

Claims 21-46 and 48-61 are pending.

The rejection under 35 U.S.C. §102(b)

The rejection of claims 21-30, 50, and 52 as being anticipated by Boothby et al., 1986, Cornell Vet. 76:188-197 (Boothby I) was maintained.

The Applicants respectfully traverse this rejection since it depends on an unreasonable interpretation of the term "incidence." The Office Action states that this rejection is based on the disclosure of Boothby I at page 194. See the Office Action, page 4, lines 14-18:

> Boothby I teaches that at weeks 12-15, 16 quarters or (4 cows) were infected with *Mycoplasma* (page 194) and at weeks 15.5 and 19.5 all 16 quarters (4 cows) were culture-negative for M. bovis (page 194). Therefore, the prior art teaches the claimed invention based on Applicant's definition of the term "incidence."

This portion of Boothby I refers to infected quarters in which the infection resolves itself over time. This can be seen by examining the entire two paragraphs which the Office Action refers to:

> During the acute phase of the experimental *M. bovis* infection (weeks 12-15), all 16 challenged quarters from vaccinated and control groups, and most unchallenged quarters from both the control (7 of 8) and the vaccinated (6 of 8) groups developed an *M. bovis* infection. Mean numbers of organisms were almost 10^9 cfu/ml in challenged quarters but were less than 10^5 cfu/ml in unchallenged quarters. By week 14, all unchallenged quarters on the vaccinated group (except for 10^1 cfu/ml from one quarter at week 15) had resolved the infection, while about 50% of similar quarters on the control cohort remained infected. [underscoring added]
>
> During the post-acute period (weeks 15.5-19.5) all of the 16 quarters (challenged and unchallenged) from the 4 vaccinated cows became culture-negative for mycoplasmas. Among the control cohort, about 25% of unchallenged quarters and about half of the challenged quarters remained infected with *M. bovis*.

It is clear that the numbers Boothby I cites and that are referred to in the Office Action pertain to differences in duration of infection, i.e., the decline in number of infected quarters over time which results from the resolution of infections in already infected quarters. Boothby I itself states this. See page 194, first two sentences, under the heading "Discussion," i.e., the sentences immediately preceding the paragraphs quoted above:

> There was little or no difference in number of infected quarters on vaccinated and control cows. Differences did, however, emerge with respect to duration of infection and the inflammatory responses. [underscoring added]

See also page 190, 4th paragraph:

> No difference was noted between unchallenged quarters which had been vaccinated and those which had both been vaccinated nor between vaccinated and unvaccinated challenged quarters for the variables under consideration (mycoplasmal infection and cellular inflammatory response).

Although Boothby I disclosed administering killed *M. bovis,* Boothby I did not disclose that the number or percentage of cows showing clinical symptoms of mastitis was less after such administering than before such administering, as required by the presently amended claims. The cows in Boothby I were free of clinical symptoms of mastitis before Boothby I administered killed *M. bovis* to them. See the sentence bridging pages 189-190: "During this time [i.e., before the experiments began] the cows showed no clinical mastitis ..." Boothby I administered killed *M. bovis* to the cows at weeks 0 to 8 of the experiment. See page 190, 6th paragraph: "The four vaccinated cows were inoculated with 2 ml of antigen ... at 3 locations subcutaneously at weeks 0, 2, 4 and with 3 mls ... by intramammary infusion at weeks 6 and 8." At week 12, Boothby I infected the cows with *M. bovis*. See page 190, 2nd paragraph: "Experimental intramammary challenge exposure was performed one week after all the cows had calved (week 12)."

Thus, before Boothby I administered killed *M. bovis*, the number and percentage of cows showing clinical symptoms of mastitis was zero. Accordingly, the number and percentage of cows showing clinical symptoms of mastitis cannot have been less after, as

opposed to before, Boothby I administered killed *M. bovis* because Boothby I began with zero cows showing clinical symptoms of mastitis and there could not have been less than zero cows showing clinical symptoms of mastitis after Boothby I administered killed *M. bovis*.

The Office Action is interpreting a reduction in the term "incidence" as including a reduction in the duration of infections in cows that are already infected with *M. bovis*. This is an unreasonable interpretation because it is contrary to how the specification refers to a reduction in "incidence" and it is contrary to how the term "incidence" is used in art, as shown by the evidence of record.

The specification

The specification consistently uses a reduction in "incidence" to refer to a reduction in the number or percentage of cows showing clinical symptoms of mastitis after vaccination as compared to before vaccination. The specification does not use a reduction in "incidence" to refer to the resolution of infection in cows that are already infected with *M. bovis*. See page 19, lines 17-31:

> Comparative results were used to measure efficacy of the vaccine. Samples taken from all animals presenting with clinical mastitis were cultured by an independent laboratory to monitor the absence or presence of *Mycoplasma bovis* infection of the mammary gland. Field evaluations were made by comparing clinical incidence of mastitis caused by *Mycoplasma bovis* following herd vaccination to the base line herd incidence prior to vaccination. Results were as follows:
>
> Pre Vaccination Base Line Incidence:
> 155 confirmed positive clinical Mycoplasma bovis infections
>
> Post Vaccination Herd Incidence:
> 1st year following vaccination:
> 24 confirmed positive clinical Mycoplasma bovis infections
> 2nd year following vaccination:
> 1 confirmed positive clinical *Mycoplasma bovis* infection.

This passage describes the results of a field trial of the claimed vaccine. The vaccine was evaluated by counting the number of cows with clinical mastitis before and after vaccination. The numbers of cows so obtained were referred to by the term "incidence."

This use of the term "incidence" is also seen in the specification at page 21, lines 11-15:

> Following vaccination of a significant portion of the herd at Site 1 and Site 2, the incidence of mycoplasma was greatly reduced. From January 1, 2000 to July 18, 2000, there were only 10 animals reported positive for *Mycoplasma bovis* at each site. This reduction in the incidence of *Mycoplasma* positive mastitis cows was regarded as a significant reduction by the operators of Sites 1 and 2.

See also the specification at page 22, line 28 to page 23, line 1:

> Following the initiation of the vaccination regime for the herd in February, 2000, a veterinarian monitored the herd for the incidence of *M bovis*. The dairy reported in September 2000 that there were no confirmed cases of *Mycoplasma* in vaccinated animals, despite the continued challenge from the presence of confirmed, infected nonvaccinated animals.

The evidence of record

The Medical Dictionary Online, available at http://www.online-medical-dictionary.org/omd.asp?q=incidence[1] states that "incidence" is "The number of new cases of a given disease during a given period in a specified population." The portion of Boothby I cited in the Office Action does not represent a description of a reduction in "incidence" of infections, as that term is defined in The Medical Dictionary Online.

Epidemiology, Gordis, Third Ed., 2004, Elsevier Saunders, Philadelphia, PA. (Gordis) uses the term "incidence" in a way that is inconsistent with the interpretation of the

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[1] A copy of the entry for "incidence" from The Medical Dictionary Online was submitted as Exhibit A accompanying the Amendment filed March 14, 2006.

Office Action. See page 33, left column: "The *incidence* of a disease is defined as the number of new cases of a disease that occur during a specified period of time in a population at risk for developing the disease." [italics in original] See also page 33, paragraph bridging left and right columns: "Incidence is a measure of events – the disease is identified in a person who develops the disease and did not have the disease previously." [underscoring added] The Applicants note that Gordis's understanding that the term "incidence" is only applied when the person "did not have the disease previously" rules out the application of the term "incidence" to the situation described in Boothby I.

The Office Action refers to no evidence where the term "incidence" is applied to the situation described in Boothby I. In view of this, the Applicants believe that this rejection is in error and the present claims are not anticipated by Boothby I.

Nevertheless, in the interests of expediting prosecution, claim 21 has been amended to recite that "the number or percentage of bovine animals that show clinical symptoms of mastitis is less after such administering than before such administering."[2] This amendment makes it even clearer that the claims are not anticipated by Boothby I since Boothby I does not disclose a reduction in infections after, as compared to before, Boothby I administered killed *Mycoplasma bovis* to the cows.

In view of the above, it is respectfully requested that this rejection be withdrawn.

The rejections under 35 U.S.C. §103(a)

The rejection of claims 21-31, 50 and 52 as being obvious over Boothby I in view of Koski et al., 1976, J. Biological Standardization 4:151-154 (Koski) was maintained.

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[2] Claims 50 and 53 have been similarly amended.

As discussed above, Boothby I does not disclose the limitation of claims 21-30, 50, and 52 that "the incidence of mastitis in the bovine animals is reduced." Boothby I also does not suggest this limitation, or teach how to obtain this limitation with a reasonable expectation of success. Therefore, Boothby I does not make obvious claims 21-31, 50, and 52.

Adding Koski to Boothby I does not cure the defects of Boothby I. There is no mention of mastitis in Koski. Accordingly, Koski does not disclose or suggest the limitation that "the incidence of mastitis in the bovine animals is reduced." Therefore, the combination of Boothby I and Koski does not make obvious claims 21-31, 50, and 52.

Claim 31 depends from claim 30 and adds the limitation that "the *Mycoplasma bovis* biotype has been inactivated by treatment with β-propiolactone." Koski was cited in the Office Action for the proposition that it was known in the art to inactivate mycoplasmas with β-propiolactone. Therefore, it supposedly would have been obvious to combine Koski with Boothby I in order to arrive at the inactivated *Mycoplasma bovis* vaccine used in the methods of the present invention.

However, it would not have been obvious to combine Koski with Boothby I because:

- Koski's disclosure is directed to mycoplasmas other than *Mycoplasma bovis*; and
- Koski taught the inactivation of mycoplasmas for reasons other than for the production of vaccines against mycoplasma-caused diseases.

Koski disclosed the inactivation of *Mycoplasma gallisepticum, Mycoplasma canis,* and *Acholeplasma laidlawii*. Koski did not disclose the inactivation of *Mycoplasma bovis.*

Koski's purpose in inactivating mycoplasma was to reduce the level of mycoplasma contamination in vaccines that were directed to other microorganisms, i.e., microorganisms

other than mycoplasma. See page 151: "Because the U.S. Department of Agriculture ... requires a test for mycoplasma in vaccines intended for veterinary use it was of interest to establish whether these agents which are used to inactivate vaccines would also inactivate contaminating mycoplasmas."

Since Koski is directed to reducing the level of mycoplasmas in vaccines against microorganisms other than mycoplasmas, one of ordinary skill in the art would not combine Koski with Boothby I. And even if such a combination were made, the most that could be arrived at would be the inactivation of *Mycoplasma bovis* contaminants in vaccines directed to other microorganisms. But all the present claims are directed to methods of immunizing bovine animals to reduce the incidence of mastitis caused by *Mycoplasma bovis* in those animals. Nothing in Koski provides a reasonable expectation that inactivating *Mycoplasma bovis* contaminants in vaccines directed to other microorganisms would result in a vaccine that could reduce the incidence of *Mycoplasma bovis*-caused mastitis. Koski does not even mention mastitis. One of ordinary skill in the art would have no reason to use any vaccines produced by the combination of Koski and Boothby I to immunize bovine animals against mastitis and would have no reasonable expectation that the use of any vaccines produced by the combination of Koski and Boothby I would be successful in reducing the incidence of mastitis.

Furthermore, additional considerations make it clear that claim 31 is not obvious. The Declaration of Dr. Joan D. Leonard, filed March 14, 2006, establishes the following relevant facts:

- The prior art disclosed many possible inactivating agents to choose from in addition to β-propiolactone (¶¶ 7-9 of the Declaration of Dr. Joan D. Leonard);

• There was no guidance in the prior art as to which inactivating agent might lead to the production of a vaccine that reduced the incidence of mastitis (¶ 10 of the Declaration of Dr. Joan D. Leonard); and

• It was surprising that inactivation with β-propiolactone would lead to a vaccine that reduced the incidence of mastitis (¶ 15 of the Declaration of Dr. Joan D. Leonard).

In view of this lack of guidance in the prior art with respect to the choice of β-propiolactone as inactivating agent and the surprising effect of β-propiolactone in producing a vaccine that reduced the incidence of mastitis, claim 31 must be viewed as being non-obvious over the prior art.

Furthermore, Dr. Leonard also explained that there was a long felt but unsatisfied need in the art for a *Mycoplasma bovis* vaccine that could reduce the incidence of mastitis. Dr. Leonard cites several publications[3] which indicate that such a vaccine would have been desirable but did not exist prior to the present invention. See the Declaration of Dr. Joan D. Leonard, at ¶¶ 11-14.

In addition to the above considerations, there are further publications that teach away from the present claims and thus indicate that the present claims are non-obvious. Boothby et al., 1986, Can. J. Vet. Res. 50:200-204 (Boothby II)[4], studied formaldehyde-killed *Mycoplasma bovis*. Boothby II tested whether killed *Mycoplasma bovis* would be effective as a vaccine against bovine mastitis and found that it was not.[5] Thus, Boothby II was

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[3] These publications cover a period from long before the present invention (1993) to soon after the present invention (2001).

[4] A copy of Boothby II was enclosed with the Information Disclosure Statement filed April 8, 2004.

[5] Despite their prior exposure to killed *Mycoplasma bovis*, the incidence of mastitis in the treated cows in Boothby II was not reduced (see page 202, middle column: "All experimentally challenged quarters became infected ...").

unsuccessful. Certainly it must be admitted that failure is a deterrent. The skilled person therefore would have been deterred by Boothby II from using inactivated *Mycoplasma bovis* to immunize bovine animals to reduce the incidence of mastitis and thus would have been deterred from seeking the solution provided by the Applicants.

Moreover, the treated animals in Boothby II showed significant and persistent reductions in the level of milk production. The control cows exhibited a smaller and more transient drop in milk production. See Figure 2 on page 202 for a comparison of treated and control cows. Thus, not only did the killed *Mycoplasma bovis* fail to reduce the incidence of mastitis in the treated cows, but it caused milk production to be even worse than it would have been had the cows not been treated. Since an important purpose for having dairy herds is to produce milk, the skilled person would certainly be deterred by a result that decreased the production of milk.[6] Given that Boothby II would have deterred the skilled person from immunizing bovine animals as claimed in two major respects – lack of efficacy and decrease in milk production – Boothby II must be seen as teaching away from the Applicants' invention. See, e.g., *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998): "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant."

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[6] This is recognized by Boothby II at page 200, right column, where it is stated: "If prophylactic vaccination is to be efficacious, it must have minimal effects on the health and productive capabilities of the cow."

Similarly, in Rosenbusch, 1998, 12th International Organisation of Mycoplasmology Conference, p. 185 (Rosenbusch)[7], the administration of inactivated *M. bovis* not only failed to confer protection against respiratory disease but was actually more detrimental than no administration at all. Rosenbusch reported that, following challenge: "A lung lesion score was combined with scores for febrile response and cultural reisolation of challenge to determine if a calf was affected or not. Only 1/5 of sham-vaccinated calves were affected, while 4/5 vaccinated calves were affected regardless of oil adjuvant used." Such failure to protect, combined with more harm to the vaccinated calves than to the sham-vaccinated calves, would have deterred the skilled person from attempting to make the present invention and thus teaches away from the present invention.

In contrast to Boothby II and Rosenbusch, the Applicants provided an invention which not only prevents disease but also is safe in that it preserves the health and well-being of the vaccinated animals. Most surprisingly, especially in view of prior art such as Boothby II and Rosenbusch, which taught that prior attempts to produce a *Mycoplasma bovis* vaccine led to products that caused unacceptably severe side effects, the vaccine of the present invention does not have a deleterious effect on the vaccinated animals. See the specification, at page 20, lines 1-2: "No injection reactions were observed. No inflammatory udder reactions were observed." See also the specification, at page 22, lines 20-22: "[T]he vaccinated animals performed well as measured by days to market and rate of gain, both important indicators of a calf s health and well-being." Although the specification does not explicitly mention milk production, the skilled person would understand that, since the specification does explicitly state that the vaccinated animals' "health and well-being" were not detrimentally effected by the vaccine, milk production would not have been compromised.

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[7] A copy of Rosenbusch was enclosed with the Information Disclosure Statement filed April 8, 2004.

The Applicants submit that the combination of high efficacy and no deleterious effect on the vaccinated animals' health and well-being is surprising in view of the prior art's failure to achieve this combination and leads to the conclusion that the present claims are non-obvious.

In view of the above, it is respectfully requested that this rejection be withdrawn.

The rejection of claims 21-38, 42, 50, and 52 as being obvious over Boothby I and Koski and further in view of Poumarat et al., 1994, Veterinary Microbiology 40:305-321 (Poumarat) was maintained.

As discussed above, the combination of Boothby I and Koski does not make obvious claims 21-38, 42, 50, and 52 since the combination of Boothby I and Koski does not disclose or suggest the limitation that "the incidence of mastitis in the bovine animals is reduced." Poumarat also does not disclose or suggest this limitation. Thus, adding Poumarat to the combination of Boothby I and Koski does not make obvious claims 21-38, 42, 50, and 52.

In addition, claims 32-38 and 42 contain the limitation that at least two inactivated *Mycoplasma bovis* biotypes are administered. Poumarat was cited in the Office Action for the proposition that it would have been obvious to administer at least two inactivated *Mycoplasma bovis* biotypes. The Office Action's reasoning in support of this proposition is found at page 9, lines 16-20:

> One of ordinary skill in the art would interpret the teachings of Poumarat et al differently than Applicants' interpretation because Poumarat et al teach that there is a marked intraspecies genomic heterogeneity among isolates of *Mycoplasma bovis* collected from different geographic origins and that antigenic variability must be taken into account in developing diagnostic and vaccination strategies.

Even assuming, *arguendo*, that Poumarat teaches that "there is a marked intraspecies genomic heterogeneity among isolates of *Mycoplasma bovis*" and that Poumarat teaches that "antigenic variability must be taken into account," Poumarat nevertheless teaches away because Poumarat teaches that this "marked intraspecies genomic heterogeneity" does not translate into "antigenic variability" such that it would be beneficial to include more than one type of *Mycoplasma bovis* in a vaccine. In this way, Poumarat teaches away from the administration of at least two inactivated *Mycoplasma bovis* biotypes.

Poumarat divided *Mycoplasma bovis* isolates into 13 different "genomic groups." Poumarat then looked at the antigenic variability between and among these genomic groups. Although Poumarat found much antigenic variability, this variability did not correlate with membership in any particular genomic group. In other words, the same amount of antigenic variability could be found within groups as between groups. See page 318, 2nd paragraph:

> Antigenic profiles of the *M. bovis* strains obtained by immunoblotting with J008 calf serum differed markedly one from the other, the heterogeneity being equally great among strains belonging to the same genomic group and those coming from different genomic groups. There appeared to be no relation between the genomic variability of *M. bovis* and the antigenic variability ...

Because Poumarat teaches that antigenic variability is as great within *Mycoplasma bovis* groups as across *Mycoplasma bovis* groups, Poumarat teaches that there would be no gain in antigenic variability from including more than one type of *Mycoplasma bovis* in a vaccine. That is, there would be no point in having more than one type of *Mycoplasma bovis* in a vaccine. Poumarat thus discourages one of ordinary skill in the art from including more than one biotype in a vaccine and therefore Poumarat teaches away from claims 32-38 and 42.

Poumarat's teaching away is especially pertinent in connection with claim 42. This claim requires that the at least two biotypes be genetically different, as judged by analysis of DNA or RNA. Poumarat teaches that such genetic differences are irrelevant with respect

to antigenicity since Poumarat teaches that there appears to be "no relation between the genomic variability of *M. bovis* and the antigenic variability." One of ordinary skill in the art would interpret this as a teaching that nothing is to be gained from including biotypes that are genetically different in a vaccine and thus would be led away from the invention of claim 42.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 21-38, 42-45, and 48-57 were rejected as being obvious over Boothby I, Koski, and Poumarat, and further in view of Rawadi, 1998, Methods in Molecular Biology 104:179-187 (Rawadi).

As discussed above, the combination of Boothby I, Koski, and Poumarat does not make obvious claims 21-38, 42-45, and 48-57 because the combination of Boothby I, Koski, and Poumarat does not disclose or suggest the limitations of those claims with respect to incidence of mastitis and/or administration of at least two inactivated *Mycoplasma bovis* biotypes. Rawadi does not disclose or suggest these limitations either. Therefore, adding Rawadi to the combination of Boothby I, Koski, and Poumarat does not make obvious claims 21-38, 42-45, and 48-57.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 21-39, 41-45, and 48-57 were rejected as being obvious over Boothby I, Koski, Poumarat, and Rawadi, and further in view of U.S. Patent No. 4,425,330 (Norcross).

As discussed above, the combination of Boothby I, Koski, Poumarat, and Rawadi does not make obvious claims 21-39, 41-45, and 48-57 because the combination of Boothby I, Koski, and Poumarat does not disclose or suggest the limitations of those claims with respect to incidence of mastitis and/or administration of at least two inactivated *Mycoplasma bovis* biotypes. Norcross does not disclose or suggest these limitations either. Therefore, adding Norcross to the combination of Boothby I, Koski, Poumarat, and Rawadi does not make obvious claims 21-39, 41-45, and 48-57.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 21-45, and 48-57 were rejected as being obvious over Boothby I, Koski, Poumarat, and Rawadi, and further in view of Straub, 1991, Comp. Immunol. Microbiol. Infect. Dis. 14:175-186 (Straub).

As discussed above, the combination of Boothby I, Koski, Poumarat, and Rawadi does not make obvious claims 21-45, and 48-57 because the combination of Boothby I, Koski, and Poumarat does not disclose or suggest the limitations of those claims with respect to incidence of mastitis and/or administration of at least two inactivated *Mycoplasma bovis* biotypes. Straub does not disclose or suggest these limitations either. Therefore, adding Straub to the combination of Boothby I, Koski, Poumarat, and Rawadi does not make obvious claims 21-45, and 48-57.

In view of the above, it is respectfully requested that this rejection be withdrawn.

<u>The rejections under 35 U.S.C. §112</u>

Claim 25 was rejected as being indefinite because of the recitation of "REGRESSIN®."

Claim 25 has been amended to delete this recitation. Accordingly, it is respectfully requested that this rejection be withdrawn.

Claims 21-46 and 48-61 were rejected as being indefinite because of the recitation of the phrase "whereby the incidence of mastitis in the bovina animals is reduced." According to the Office Action, this phrase is indefinite because "there is no indication that the bovine animals of the preamble have mastitis."

The Applicants respectfully traverse this rejection. A claim is indefinite only if one skilled in the art would not understand what is claimed when the claim is read in light of the specification. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 U.S.P.Q.2d 1081, 1088 (Fed. Cir. 1986) ("A decision on whether a claim is invalid under § 112, 2d ¶, requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification."). Method claims are not indefinite if one skilled in the art can determine whether a particular process is within the scope of the claims. *Application of Mercier*, 185 USPQ 774, 780, 515 F. 2d 1161, 1168 (CCPA 1975): "[I]f one can determine whether a particular catalytic process for splitting acetals and hemi-acetals is or is not within the scope of a claim, the claim fulfills its purpose as a definition."

One skilled in the art would understand from the specification, in particular the working examples at pages 18-23, that the claims are directed to methods of immunizing cows where the number or percentage of cows showing clinical symptoms of mastitis is reduced after immunization as compared to before immunization. Furthermore, one skilled

in the art would be able to determine whether a particular process is or is not within the scope of the present claims by determining whether the number or percentage of cows showing clinical symptoms of mastitis is reduced after immunization as compared to before immunization. There is no need to specify that the cows have mastitis in order for the specification to be so understood or to determine if a particular process falls within the scope of the present claims. This rejection appears to be based on the view that the claims are directed merely to methods of reducing the duration of infections. As discussed above in connection with the rejection under 35 U.S.C. §102(b), this view is untenable. Accordingly, it is respectfully requested that this rejection be withdrawn.

Claims 21-46 and 48-61 were rejected as being indefinite because, according to the Office Action the specification fails to use the term "incidence" as it is used in Epidemiology, Gordis, Third Ed., 2004, Elsevier Saunders, Philadelphia, PA. (Gordis).

The Applicants respectfully traverse this rejection. The Applicants respectfully submit that the relevant issue is not whether the specification uses the term "incidence" precisely as it is used in a particular publication such as Gordis. Instead, the relevant issue is whether the use of the term "incidence" in the claims is such that one of ordinary skill in the art would understand what the claims cover, when the term "incidence" is read in light of the specification. As discussed above in connection with the rejection under 35 U.S.C. §102(b), the specification uses a reduction in "incidence" to mean a reduction in the number or percentage of cows showing clinical symptoms of mastitis after vaccination as compared to before vaccination. Thus, reading the claims in light of the specification would lead one of ordinary skill in the art to understand exactly what is being claimed. In view of this, the claims are definite.

In view of the above, it is respectfully requested that this rejection be withdrawn.

The time for responding to the Office Action was set for September 15, 2006. Enclosed herewith is a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of this response. Please charge any corresponding fees for the Petition to Kenyon & Kenyon's Deposit Account No. 11-0600.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

Respectfully submitted,

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